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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,838	07/14/2003	Scott Selmer Johnson	1388-010A	7633

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CASTLE ROCK, CO 80108

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,838	<b>Applicant(s)</b> JOHNSON, SCOTT SELMER	
	<b>Examiner</b> Ashwin Mehta	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2262004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Request under 37 CFR 1.105</u> .       |

### **DETAILED ACTION**

1. The originally filed application contained claims numbering 1-32. The preliminary amendment filed July 14, 2003 directed the cancellation of claims 1-45 and introduced new claims 46-48. However, the application never contained claims numbered 33-45. As per 37 CFR 1.126, claims 46-48 were renumbered 33-35, respectively. Applicants also filed a preliminary amendment on February 26, 2004, canceling claims 1-48 and introducing claims 49-57. Again, as per 37 CFR 1.126, claims 49-57 were renumbered 36-44, respectively.

### ***Priority***

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant

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application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the

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petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Claim Objections***

3. Claims 36, 37, and 41 are objected to because of the following informalities: the recitation, --been deposited under—should be inserted before “ATCC” in the claims.

Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claim 36 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,642,440. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same product. Instant claim 36 is drawn to a male-sterile corn plant produced by growing the seed of corn line 7SH385, seed of which having been deposited with the ATCC under Accession No. PTA-5203. Patented claim 2 is drawn to a corn plant, or parts thereof, produced by growing seed of corn inbred line designated 7SH385, which was deposited with the ATCC under Accession No. PTA-5203. Patented claim 2 does not indicate that the plant is male sterile. However, the plants encompassed by both claims are identical.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 39 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 39: the claim appears to omit an essential step, such omission amounting to a gap between the steps. The claim is directed to corn seed produced by growing the F1 hybrid corn plant of claim 38 and harvesting the resultant corn seed. However, the F1 hybrid corn plant will not produce seed unless it is pollinated. The claim does not mention any crossing step. See MPEP § 2172.01.

In claim 42: the recitation, “substantially all physiological and morphological characteristics” in line 2 of part d) renders the claim indefinite. The term, “substantially” is a relative term that has not definite meaning. When does a plant not have substantially all physiological and morphological characteristics of the corn plant 7SH385?

Further in claim 42: the claim is indefinite because the preamble is inconsistent with the last recited step. Line 1 of the claim indicates that it is directed to a method of introducing a desired trait into corn inbred line 7SH385. However, the last line of the claim indicates that a “converted progeny plant comprising the desired trait” is produced. It is unclear if the converted progeny plant is the same as line 7SH385 further comprising the desired trait, especially given that step d) only requires selected progeny to comprise “substantially” all physiological and morphological traits of 7SH385. It is also unclear what is meant by “converted”.

In claim 43: the recitations, “yield enhancement,” “enhanced nutritional quality,” and “yield stability” are relative terms that have no definite meaning, making the metes and bounds of the claim unclear. What one may consider an enhancement may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they enhanced?

Further in claim 43: the claim includes “male sterility” in the Markush group of desired traits. However, claim 1 indicates corn inbred line 7SH385 is male-sterile. It is unclear how the method of claim 43 affects corn plant 7SH385, when the selected trait to be introduced is one that is already present?

Further in claim 43: the recitation, “industrial usage” renders the claim indefinite. It is unclear what defines this trait.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes some morphological characteristics of a corn plant designated “7SH385” (pages 11-13 and 31-37).

A review of the full content of the specification indicates that seed of corn plant 7SH385, hybrid seed produced by crossing a 7SH385 plant with any other corn plant, and the seed and plants of subsequent generations, are essential to the operation and function of the claimed invention.

A review of the language of claims 37-38 indicates that the claims are drawn to a genus, i.e., any and all F1 hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing corn plant 7SH385 with a second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different F1 hybrid species of the genus, since each hybrid has one non-7SH385 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-7SH385 inbred parent. As a result, the complete genomic



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structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ. A review of the language of claim 39 indicates that it is drawn to a hybrid corn plant produced by growing the F1 hybrid corn plant of claim 38 and harvesting the resulting seed. A cross is required for the F1 hybrid corn plant to produce seed. Therefore, the seed of claim 39 represent the second generation descendants of 7SH385. Even further variation exists among each of the second generation plants, as they would comprise less of the genome of 7SH385.

A review of the language of claim 40 indicates that it is drawn to a method for producing corn seed, wherein the method comprises crossing the hybrid corn plant of claim 38 with another corn plant. The claim therefore requires F1 generation plants.

The specification does not describe the claimed genus of hybrid corn plants. Hybrids produced by crossing 7SH385 with other corn plants would, of course, produce plants that do not express the same traits as 7SH385. The description of 7SH385 and the limited information regarding its traits on pages 11-13 and 31-37 of the specification do not provide any information concerning the morphological and physiological characteristics of its descendants. As each hybrid has one parent that is not shared, each of the hybrids would have different genomes and express different sets of traits, and therefore are not representative of one another. In view of these considerations, a person of skill in the art would not have viewed the disclosure as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced from 7SH385. Even greater variation exists among each plant encompassed by claim 39, as they would contain even less of the genome of corn plant 7SH385.

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Claim 41 is directed to a method of producing inbred corn seed 7SH385, comprising planting a collection of seed that comprises seed of inbred corn plant 7SH385 and hybrid seed that have 7SH385 as one of its parents. The method requires hybrid corn seed as part of its starting material.

As F1 seeds and plants are required for the claimed methods, the methods are not described, either. The Federal Register (64 Fed. Reg. 71427, 71428 (1999), Comment No. 4) indicates that a suggestion was made that the written description guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those whose patentability rests in the steps of the process itself, and that this suggestion was adopted. The patentability of the method claims do not lie in the method steps, which require the simple acts of crossing plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method claims are not described, as the specification does not sufficiently describe the genus of hybrid plants, and any progeny of subsequent generations, for the reasons discussed above. Given the breadth of the claims encompassing all hybrid corn seeds and plants produced by crossing 7SH3895 to any other inbred corn plant and hybrid seed produced by growing F1 hybrid corn plants and harvesting seed, it is submitted that the specification fails to provide an adequate written description of the multitude of corn seeds and plants encompassed by the claims.

7. Claims 36 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 36 is directed to a male-sterile corn plant produced by growing seed of corn line 7SH385, seed of which has been deposited under ATCC Accession No. PTA-5203. However, the specification does not indicate that this plant is male-sterile. The specification indicates on page 7, paragraph [0024], that the inbred *may further* comprise a cytoplasmic factor capable of conferring male sterility (emphasis added). However, neither the instant specification, nor parent application 09/921,651, states that inbred corn plant 7SH385 *is* male-sterile. Further, U.S. Patent No. 6,642,440, which issued from 09/921,651, claims a method for producing a transgenic corn plant, comprising transforming inbred corn plant 7SH385 with a transgene that confers male sterility. Also claimed in the patent is the transgenic corn plant produced by said method. Therefore, as originally disclosed, a gene that confers male sterility was required to be introduced into 7SH385 plants to make it male-sterile. The recitation, “male-sterile” in instant claim 36 is NEW MATTER and must be removed.

Claim 42 is broadly drawn towards a method of introducing a desired trait into corn inbred line 7SH385, comprising steps which include crossing 7SH385 with a second corn plant comprising the desired trait, selecting progeny plants comprising the trait, crossing the selected progeny with 7SH385, selecting progeny from that cross that comprise the trait, and repeating the crossing and selection step one or more times to produce a converted progeny plant comprising the desired trait. Dependent claim 43 limits the identity of the desired trait, and claim 44 is drawn to any plant produced by the method, comprising the trait.

The specification briefly and generally discusses backcross breeding to introduce a desired trait into an inbred line on page 4 (paragraph [0013]). The specification also discusses “single gene conversions” on pages 28-30. However, the specification does not indicate that such protocols comprise selecting progeny plants that comprise the desired trait and only “substantially” all physiological and morphological characteristics of corn plant 7SH385. The specification also does not provide written description support for the recitation, “one or more times”. While the specification indicates that the progeny are repeatedly crossed to the recurrent (original inbred) parent, it does not provide support for performing only two such crosses, which is encompassed by claim 42. The aforementioned recitations are NEW MATTER and must be removed from the claims.

8. Claims 36-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 36 is drawn to a male-sterile corn plant produced by growing seed of corn line 7SH385, seed of which has been deposited under ATCC Accession No. PTA-5203. Claims 37-44 are drawn to progeny of inbred corn plant 7SH385, or methods requiring 7SH385 plants.

However, it is unclear which deposit Applicant is relying on. Claim 36 recites “ATCC Accession No. PTA-5203.” However, the deposit information in the specification on page 37 indicates that a deposit of seed is maintained by Agrigenetics, Inc., and that a deposit with the ATCC will be made upon allowance. It does not mention an accession number. It is noted that

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U.S. Patent No. 6,642,440 indicates that seed of 7SH385 have been deposited with the ATCC under Accession No. PTA-5203, and that Applicant may be relying on that deposit information to make the seed known and readily available to the public. However, the instant application does not contain a claim of priority to U.S. Application 09/921,651.

If the seeds have not yet been deposited: if the deposit will be made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained. See 37 CFR 1.801-1.809.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Of note: a search of the ATCC catalog revealed that accession number PTA-5203 is not listed therein. Applicants should verify that all restrictions upon availability to this deposit have been irrevocably removed.

9. Claims 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of introducing a desired trait into corn inbred line 7SH385, comprising crossing a plant of said line with a second corn plant comprising the desired trait, selecting progeny that comprise the trait, crossing the progeny to 7SH385 and selecting further progeny comprising the desired trait and substantially all physiological and morphological characteristics of 7SH385, and repeating the backcrossing steps one or more times to produce a converted plant comprising the desired trait; a plant produced by the method.

The specification briefly and generally discusses backcross breeding to introduce a desired trait into an inbred line on page 4 (paragraph [0013]). The specification also discusses “single gene conversions” on pages 28-30. The specification indicates that such backcrosses are repeated to produce a plant having the desired trait and essentially all of the desired

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morphological and physiological characteristics of the recurrent parent (paragraph [0134], for example).

However, the specification does not teach any plants produced by the claimed method, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the desired trait, especially after just backcrosses, as broadly encompassed by the claims. It is not clear that single genes may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety. Plant breeding, including corn breeding, is unpredictable, due to linkage drag, linkage disequilibrium, and/or epistatic effects. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), and Murray et al. (In Proc. 43<sup>rd</sup> Annual Corn& Sorghum Industry Research, Wilkinson et al., eds., American Seed Trade, Assn., 1988, pages 72-87) for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and

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therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Murray et al. teach that linkage drag is a common phenomenon in corn breeding, and that the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1% (see, e.g., pages 82-84). Thus, outcrosses to produce corn plants containing an introgressed gene would also introgress unwanted linked genetic material from the donor parent. In the absence of repeated generations of backcrossing and selection for the recipient parent's traits, this unwanted genetic material would never be lost, and the claimed plants could not be produced. The current claims encompass performing as few as two backcrosses to recipient corn plant 7SH385. The plant produced by the method would not have recovered the characteristics of 7SH385 with only two backcrosses. In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of introgression taught in the prior art, in order to yield the claimed plants. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

***Claim Rejections - 35 USC § 102 & 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 37-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Marshall et al. (U.S. Patent No. 6,284,955 issued September 4, 2001).

The instant claims are broadly drawn towards any F1 hybrid corn seed produced by crossing a first corn plant with designated "7SH385" with another different inbred corn plant; or a hybrid plant produced by growing said hybrid seed; or a corn seed produced by growing said F1 hybrid plant and harvesting the resulting seed; or a method of producing corn seed comprising crossing the F1 hybrid corn plant and harvesting the resultant corn seed.

Marshall et al. teach F1 hybrid corn seeds, and corn plants produced by growing said seed, parts of said plant, and seed produced by crossing said hybrid plant with another corn plant (claims). The corn seeds and plants may have been produced from a method different from those of the instantly claimed corn seeds and plants. However, the instantly claimed products do not appear to differ from the products taught by the reference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

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the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The instant claims do not recite any limitation(s) that would distinguish the products from those of the reference.

11. Claim 44 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan (U.S. Patent No. 6,239,334, issued May 29, 2001).

The claim is broadly drawn towards any plant produced by a method comprising crossing a plant of line 7SH385 with a second corn plant comprising the desired trait, selecting progeny that comprise the trait, crossing the progeny to 7SH385 and selecting further progeny comprising the desired trait and substantially all physiological and morphological characteristics of 7SH385, and repeating the backcrossing steps one or more times to produce a converted plant comprising the desired trait.

Morgan teaches a corn plant designated “F351”. The plant may have been produced from a method different from that of the instantly claimed plant. However, the plants produced by the method of instant claim 42 produced plants that only have a desired trait and “substantially” all physiological and morphological characteristics of inbred line 7SH385. The plant of the reference can be said to have a desired trait and “substantially” all physiological and morphological characteristics. The instantly claimed product does not appear to differ from the products taught by the reference. See *In re Thorpe, supra*.

12. Claims 36-44 are rejected.

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***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638

March 20, 2006

**ATTACHMENT TO OFFICE ACTION**

**Request for Information under 37 CFR § 1.105**

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least 25% of the genome of corn line 7SH385, **but** the instant specification is silent about what starting materials and methods were used to produce corn line 7SH385. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental corn lines used to produce corn line 7SH385?

Please supply all of the designations/denominations used for the original parental corn lines and line 7SH385. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce corn line 7SH385?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental corn lines or progeny therefrom been disclosed or made publicly available? If so, under what designation/denomination and under what conditions were said parental corn lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other corn lines produced by said method using said original parental corn lines, and if so, had said produced corn lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other corn lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain

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an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

  
ANNE MARIE GRUNBERG  
SUPERVISORY PATENT EXAMINER